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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Barry N. Gellman

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EXAMINER

SCHELL, LAURA C

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/757,159	Applicant(s) GELLMAN, BARRY N.	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18, 20, 22, 23, 26-28 and 30-38 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 33-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18, 20, 22, 23, 26, 28, 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11, 17, 26, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al. (US Patent No. 6,033,105) in view of Murphy (US Patent No. 6,273,916). Barker discloses the device substantially as claimed including: a delivery system (Figs. 1-5) comprising an injector system coupled to a driving system, the injector system comprising: a housing (Fig. 3a, 21/22) defining a lumen and having an output end (near 48) and a driving system connection end (near 47), the lumen comprising a proximal portion (near 47) and a distal portion (near 48/49) and the inner diameter of the proximal portion being substantially larger than the inner diameter of the distal portion (the diameter of the distal portion is smaller than that of the proximal portion); a cannula assembly (23) coupled to the output end of the housing for coupling

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to a cannula; and a mixing member (29/30, see Figs. 2 and 3a as 29/30 are connected together and form the mixing member) extending through the lumen from the driving system connection end to at least a portion of the cannula assembly (29/30 extends from the driving system connection end (as portions 35 as disclosed in Fig. 2) into the cannula assembly (as element 30)), the mixing member being rotatable within the lumen in both the proximal portion and the distal portion (29/30 rotates in both portions), wherein the mixing member comprises an elongated helical element (29/30 is helical in both portions; applicant has not claimed that it must be one continuous helix); and the driving system comprises: a drive mechanism (Figs. 1, 2 and 3a disclose that the drive mechanism can be interpreted as portion 38 as this is what connects the actuator to drive the mixing); an actuator coupled to the drive mechanism (Fig. 3a, 39) to actuate the drive mechanism; and a rotatable interfacing member (28/34 rotates in response to be actuated by the drive member and the actuator; please note that very little structure regarding the drive mechanism, actuator and rotatable interfacing member is being claimed) coupled to the drive mechanism for coupling with the mixing member to rotate the mixing member when the interfacing member is driven by the drive mechanism, wherein the mixing member is rotatable in the cannula assembly and wherein mixing occurs in the cannula assembly (mixing clearly occurs in the cannula assembly).

Barker, while disclosing that the cannula assembly is used to deliver the cement to a desired location for repairing a bone (col. 12, lines 9-16), does not disclose that the cannula assembly is a needle assembly. Murphy, however, discloses a cement delivery system which uses a vertebroplasty needle (Figs. 6-9, needle 73; col. 6, line 59 through

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col. 7, line 26) connected to a bone cement supply to delivery the bone cement to the desired site, similar to the use of Barker's assembly. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Barker's cannula assembly by changing the cannula to a needle, as taught by Murphy, in order to provide a mixing assembly that is capable of delivering the cement to a smaller, harder to reach location than a larger diameter cannula is capable of reaching.

In reference to claim 17, Barker discloses that the driving system is capable of coupling to an injector system, the injector system comprising a tubular member and a mixing member extending through the tubular member (tubular member is cannula 23 which is capable of connecting to the device, and the mixing member 30 extends through the cannula).

In reference to claim 26, Barker discloses that the mixing member comprises a helical element (30 is helical).

In reference to claims 31 and 32, Barker discloses that the injector system comprises an injectable material comprising a shear-sensitive injectable material (please note that this component is part of the injector system which is part of the intended use phrasing of the claim and therefore the driving system merely has to be capable of use with it, which it is. Also, the reference discloses that the device is used to mix bone cement which changes viscosity as it is mixed and is then subjected to shear forces when being injected through the cannula, which therefore meets Applicant's definition of a shear sensitive material).

Claims 18, 20, 22, 23, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al. (US Patent No. 6,033,105) in view of Murphy (US Patent No. 6,273,916). Barker discloses the device substantially as claimed including: a coupling system for use with a tube of a syringe (Figs. 1-5) comprising: a housing (Fig. 3a, 21/22) for coupling to the tube of the syringe, said syringe comprising a cannula assembly (23) coupled to an output end of the tube (near 48); a drive mechanism disposed within the housing (shaft 34 can be interpreted as the drive mechanism as this is what turns/rotates the mixing member); a mixing member comprising an elongated helical element for coupling to the drive mechanism (the mixing member can be interpreted as portions 35 and 30 as these are coupled to the drive mechanism 34), the mixing member extending into the tube of the syringe and being rotatable within the tube of the syringe in both the proximal portion and the distal portion (35 and 30 rotate in both portions) and at least a portion of the cannula assembly to mix and deliver an injectable from the tube of the syringe (30 rotates in the cannula assembly); and an actuator (Fig. 3a, 39) coupled to the drive mechanism to actuate the drive mechanism and thereby cause rotation of the mixing member and mixing occurs in the cannula assembly and the tube (Fig. 3a). Barker, while disclosing that the cannula assembly is used to deliver the cement to a desired location for repairing a bone (col. 12, lines 9-16), does not disclose that the cannula assembly is a needle assembly. Murphy, however, discloses a cement delivery system which uses a vertebroplasty needle (Figs. 6-9, needle 73; col. 6, line 59 through col. 7, line 26) connected to a bone cement supply to

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delivery the bone cement to the desired site, similar to the use of Barker's assembly.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Barker's cannula assembly by changing the cannula to a needle, as taught by Murphy, in order to provide a mixing assembly that is capable of delivering the cement to a smaller, harder to reach location than a larger diameter cannula is capable of reaching.

In reference to claim 20, Barker discloses that the housing comprises a mating portion, the mating portion being capable of mating with the tube of the syringe (portion near 73).

In reference to claim 22, Barker discloses that the tube of the syringe comprises an injectable material (bone cement, abstract).

In reference to claim 23, Barker discloses that the housing comprises finger grips (the edge portions of 24 are capable of being gripped by fingers and therefore can be interpreted as finger grips).

In reference to claim 28, Barker discloses that the mixing member comprises a helical element (25 and 30 are both helical).

In reference to claim 30, Barker discloses that the injector system comprises an injectable material comprising a shear-sensitive injectable material (please note that this component is part of the injector system which is part of the intended use phrasing of the claim and therefore the driving system merely has to be capable of use with it, which it is. Also, the reference discloses that the device is used to mix bone cement which changes viscosity as it is mixed and is then subjected to shear forces when being

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injected through the cannula, which therefore meets Applicant's definition of a shear sensitive material).

Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al. (US Patent No. 6,033,105) in view of Murphy (US Patent No. 6,273,916) and further in view of Critchlow et al. (US Patent No. 2003/0171712). Barker in view of Murphy discloses the device substantially as claimed except for a low torque motor, a battery or a switch. Critchlow, however, discloses a hand-held syringe (Fig. 9) with a high speed, low torque motor (paragraph [0053]), that the motor is coupled to a battery as an energy source (paragraph [0046]) and that the actuator comprises a switch (paragraph [0128]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Barker in view of Murphy with the specific motor, energy source and switch, as taught by Critchlow, in order to provide an injector system that is powerful enough to mix and inject such viscous material, as well as be hand-held and portable.

Response to Arguments

Applicant's arguments with respect to claims 11-18, 20, 22, 23, 26, 28, 30-32 have been considered but are moot in view of the new ground(s) of rejection.

In reference to the Critchlow reference, the reference is being used again as a secondary reference as it teaches that it is well known in the art to use different types of motors to drive the driving member in a mixing apparatus.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767